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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,450	11/27/2000	Wolfgang Fleischer	228.1007	9935

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DAVIDSON & DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE
14TH FLOOR
NEW YORK, NY 10018

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,450

Applicant(s)

Fleischer

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 31, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 9-14, 16-18, 22, 23, 32-51, and 55-63 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 9-14, 16-18, 22, 23, 32-51, and 55-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and amendment dated 3-31-03 are acknowledged.

Claims included in the prosecution are 1, 9-14, 16-18, 22-23, 32-51, and 55-63.

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. Claims 23, 32-39, 42-43, 51 and 55 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The issue relating to functional tissue remodeling as set forth before is maintained since applicant provides no arguments regarding this issue.**

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42 and 43 depend from either claims 22 or 23; however, claim 23 is drawn to functional remodeling. Therefore, claims 42 and 43 which recite the treatment of diseases such as HIV and bronchitis are inconsistent with the parent claim 23.

Double Patenting

The obviousness type double patenting rejections as set forth in the previous office action are maintained in abeyance to the filing of terminal disclaimers.

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 9-14, 16-18, 44-50, 58-59 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0639373 of record.

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EP discloses the same composition (note the abstract and entire article of EP). The intended use has no patentable significance in the composition claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the references do not teach or suggest the formulations in nebulized or aerosolized form as recited in independent claim 1. This argument is not found to be persuasive since EP teaches spray mist (aerosol) of the solutions (page 6, lines 48 and 49).

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 22-23, 32-43, 55-57, 60-61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP in combination with knight or Radhakrishnan or Prince or vice versa.

The teachings of EP have been discussed above.

As pointed out before. Knight discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-5 microns. The drugs include

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antibiotics, antiviral agents and steroids (note the abstract, Tables I and II, examples and claims).

As also pointed out before, Radhakrishnan discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-5 microns. The drugs include antibiotics, antiviral agents and steroids (note the abstract, Examples and claims).

Prince discloses liposome aerosol formulation for the delivery of drugs to respiratory tract. The particle sizes are 1-10 microns. The drug combination includes antibiotics, antiviral agents and steroids (note the abstract, Examples and claims).

What is lacking in EP is the teaching of the use of the composition for the treatment of diseases caused by the microbes in the respiratory tract. In the absence of showing unexpected results, it is deemed obvious for one of ordinary skill in the art to use an anti-septic agent and a wound healing promoting agent taught by EP to any part of the body including the respiratory tract, which has a microbial infection and a wound with the expectation of reasonable success since the references of Knight, Radhakrishnan and Prince show the common knowledge in the art of using a combination even for the respiratory tract. One of ordinary skill in the art would have been motivated to use PVP-iodine taught by EP as a drug in the liposomal compositions of Knight, Radhakrishnan or Prince with the expectation of obtaining similar results since PVP-Iodine is a known anti-septic agent as shown by EP. EP also does not teach the administration of the composition for the infections which occur during remodeling or repairing the lower respiratory tract.

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However, it is deemed obvious to one of ordinary skill in the art that the wound healing compositions can be applied during any state wherein the wounds are susceptible to infectious agents, with the expectation of similar anti-septic effect.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Knight, Radhakrishnan or Prince are directed to inhalable preparations and EP reference is directed to compositions and methods for external use. These arguments have not been found to be persuasive since, the references of Knight, Radhakrishnan, Prince and EP are liposomal compositions containing agents meant for treating the infectious conditions. Although the composition in EP is for external use, EP clearly teaches on page 2, lines 1-9 that the preparations are meant for application to the mucous membranes in humans and furthermore, EP is directed to the treatment of eye conditions. This is suggestive of the safe application of the compositions even for nasal or oral or tracheal mucous tissues. Furthermore, EP at the same location teaches that different antibiotics and antiseptic agents are known for the topical treatment of infectious diseases and that while antibiotics quite often lead to patient sensibilization, antiseptic agents such as PVP-iodine can prevent resistances and that they are much more rarely allergenic, as compared to antibiotics. Hence one of ordinary skill in the art would be motivated to use the compositions containing PVP-iodine of EP by inhalation route taught by Knight or Radhakrishnan or Prince.

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Note: to reduce the issues, the JP and Schreier references is withdrawn from the above rejections.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

June 25, 2003